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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,457	02/21/2002	Anne M. Pianca	98P1021US08	3029
36802	7590	06/01/2007		
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/081,457

Applicant(s)

PIANCA ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/07 has been entered.

Election/Restrictions

Claims 22 and 23 have been withdrawn from consideration as being directed to a non-elected invention as set forth in the previous action of 1/8/07. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

The affidavits filed on 8/30/04 and 4/10/07 under 37 CFR 1.131 are sufficient to overcome the Hsu et al reference. In addition, the affidavit showing diligence also shows diligence before the Chastain et al reference, but as previously discussed in the office action of 3/24/03, the declaration of 2/28/03 was ineffective since all the inventors of the subject matter claimed did not submit declarations.

The declaration filed on 2/28/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the Chastain et al reference for the following reasons.

All the inventors of the subject matter claimed have not submitted declarations. (See MPEP 715.04)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 6, 9, 12, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Chastain et al (5925073). Chastain discloses the claimed invention using an S shaped lead (figure 1) with peak to peak amplitude of 0.5-4.0 cm (column 2) and states it is used to make intermittent contact with the vessel wall (for claims 1 and 19). In addition, Chastain states that the S span is about 4-7 cm and shows in figure 1 the end of the span located 4-20 cm from the distal tip and therefore the distal electrode is anywhere from 0-13 cm away from the span and therefore within 50% of the peak to peak amplitude of the two bends. Finally, Chastain meets the claimed limitation of the electrode “coupled to...the vessel wall” since the electrode is used to deliver stimulation to the vessel wall and is coupled to the wall through the blood of the patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 11, 14, and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chastain et al. Chastain shows in figures 1, 4, and 6 the lead having non-helical bends comprising two-sides forming an angle in the range of about 45 degrees, which is in the range of 30-150 degrees. In addition, Chastain states that a guidewire is used (column 3) and therefore would require a distal opening. In regards to claim 4, Chastain will meet the intended use recitations presented in the claim since the stylet can be moved anywhere along the bends to cant the tip toward the patient's wall (the "steerable canted end" is used in claim 2 when the stylet is partially withdrawn) and since Chastain's electrode is oriented toward a wall since the electrode is oriented by the bends. Finally, for claim 18, Chastain states that a guidewire is used (column 3) and will meet the intended use recitations of adapted to engage a stylet since the lead receives a guidewire and is therefore capable of receiving/engaging a similar size device, such as a stylet (the dimensions of the stylet have not been set forth.)

In the alternative, Chastain discloses the claimed invention except for the bends having an angle of 30-150 degrees, a distal opening for a guidewire and the lead capable of engaging a

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stylet, and the tip electrode oriented toward the wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Chastain, with the bends having an angle of 30-150 degrees, a distal opening for a guidewire and the lead capable of engaging a stylet, and a tip electrode oriented toward the coronary wall since it was known in the art that heart leads having an anchor use: anchor bends having an angle of 30-150 degrees to allow the lead to easily anchor in the heart and provide good stability to prevent movement of the lead; a distal opening in the lead and the lead capable of engaging a stylet to allow the lead to be accurately placed in the heart using the guidewire and also allowing the lead to be further placed with a stylet; and the tip electrode oriented toward the coronary wall to provide physical contact with the wall for more effective stimulation.

Claims 4, 11, 14, and 18 are rejected under 35 U.S.C. 103(a) as obvious over Chastain et al.. Chastain shows in figures 1, 4, and 6 the lead having non-helical bends comprising two-sides forming an angle in the range of about 45 degrees, which is in the range of 30-150 degrees. In addition, Chastain states that a guidewire is used (column 3) and therefore would require a distal opening. In regards to claim 4, Chastain will meet the intended use recitations presented in the claim since the stylet can be moved anywhere along the bends to cant the tip toward the patient's wall (the "steerable canted end" is used in claim 2 when the stylet is partially withdrawn) and since Chastains electrode is oriented toward a wall since the electrode is oriented by the bends. Finally, for claim 18, Chastain states that a guidewire is used (column 3) and will meet the intended use recitations of adapted to engage a stylet since the lead receives a guidewire and is therefore capable of receiving/engaging a similar size device, such as a stylet (the dimensions of the stylet have not been set forth.)

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In the alternative, Chastain discloses the claimed invention except for the bends having an angle of 30-150 degrees, a distal opening for a guidewire and the lead capable of engaging a stylet, and the tip electrode oriented toward the wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Chastain, with the bends having an angle of 30-150 degrees, a distal opening for a guidewire and the lead capable of engaging a stylet, and a tip electrode oriented toward the coronary wall since it was known in the art that heart leads having an anchor use: anchor bends having an angle of 30-150 degrees to allow the lead to easily anchor in the heart and provide good stability to prevent movement of the lead; a distal opening in the lead and the lead capable of engaging a stylet to allow the lead to be accurately placed in the heart using the guidewire and also allowing the lead to be further placed with a stylet; and the tip electrode oriented toward the coronary wall to provide physical contact with the wall for more effective stimulation.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al as applied to claims 6 and 1 above.

Chastain discloses the claimed invention except for the humps being in different geometric planes. It would have been an obvious matter of design choice to one skilled in the art to modify the anchoring lead as taught by Chastain with the humps in the anchor being located in different geometric planes, since applicant has not disclosed that providing the humps in different geometric planes provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any location of the humps, such as the humps

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being located in the same plane as taught by Chastain to anchor the lead in the coronary sinus and provide contact with the wall only along the humps.

Claims 3, 7, 8, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain as applied to claims 2, 6, and 1 above. For claim 7, Chastain shows in figure 1 the bends being located 4-20 cm from the end and states the length of the bends are 4-7 cm long (column 2) and therefore provide a first bend located in the range of 0.15-0.7 inches from the distal end (in the alternative, see the rejection below).

Chastain discloses the claimed invention except for the stylet having a tapered portion, the first bend located in the range of 0.15-0.7 inches from the distal end, and the lead having a textured region of ePTFE or porous material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical electrical lead as taught by Chastain with the stylet having a tapered portion, and the lead having a textured region of ePTFE or porous material (such as silicone rubber, polyurethane, or ceramic) since it was known in the art that medical electrical leads use a stylet with a tapered portion to allow the stylet to fit in the narrow distal end of the lead and to position the lead, and that leads have a textured region of ePTFE or porous material to allow the lead to anchor in the body.

In addition, it would have been an obvious matter of design choice to one skilled in the art to modify the medical electrical lead as taught by Chastain to include ePTFE as the textured region and the first bend being located 0.15-0.7 inches from the distal end, since applicant has not disclosed that ePTFE and the first bend being located 0.15-0.7 inches from the distal end provides any criticality and/or unexpected results and it appears that the invention would perform

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equally well with any biocompatible textured material or any location of the bends, such as silicone rubber, polyurethane or ceramic for allowing the lead to anchor in the body as taught by Chastain in view of one having ordinary skill in the art for allowing the lead to anchor in the coronary sinus or such as the S-shaped or zig-zag shaped lead location of the bends as taught by Chastain to allow the lead to anchor in the coronary sinus and provide electrodes for electrical contact with the heart chambers.

Allowable Subject Matter

Claim 21 is allowed.

Response to Arguments

Applicant's arguments filed 10/26/06 have been fully considered but they are not persuasive. See the above discussion of the ineffective affidavit.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

5/29/07

GRE
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